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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 28

Serial Number: 09/020393
Filing Date: February 9, 1998
Appellant(s): Peter J. Sims

Patrea Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's Revised Brief on appeal filed 12/12/01 (Paper No. 26).

The text of those sections of Title 35 U.S. Code not included in this appeal can be found in a previous Office Action herein.

(1) Real Party of Interest.

A statement identifying the real party of interest in contained in the Brief.

(2) Related Appeals and Interferences Identified.

A statement identifying that no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the Brief.

(3) Status of Claims.

The statement of the status of claims contained in the Brief is correct.

This appeal involves claims 10-12 and 16-17 as they read on methods using anti-C9 antibodies as the elected invention are under consideration in the instant application.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the Brief is correct.

(5) Summary of Invention.

The summary of invention contained in the Brief is essentially correct.

It is acknowledged that the claims are drawn to a molecule mimicking the region of human CD59 which is both species specific and which binds to C9, thereby inhibiting complement activation mediated by formation of the human C5b-9 complex. Appellant's reliance on the important limitation of the claims that the compound must structurally mimic human CD59 amino acids 42-58, when these amino acids have the same spatial orientation as when present in the intact molecule and must specifically bind to amino acids 359 to 384 of human C9 is acknowledged.

For clarity, the instant claims have been examined and prosecuted as methods of inhibiting C5b-9 complex with antibodies that bind C9 (see Paper No. 12, page 2, section 2). Also see Issues below.

It is noted that page 5 of appellant's amendment, filed 11/15/99 (Paper No. 15), has acknowledged that "Merely because there may be an antibody which binds to C9 does not mean that it mimics the region of CD59 which is in issue; in fact, absent making the antibody by immunization with is region and then screening for efficacy in preventing human CD59 activity, it is extremely unlikely that such an antibody could be obtained. See in particular page 47 in this regard."

Page 47, paragraph 2 of the instant specification discloses that a "Fab of antibody raised against the hu C9 peptide 359-384 was tested for its capacity to inhibit the hemolytic activity of the hu C5b-9 complex, under the same condition used to evaluate the inhibitory function of CD59.

Therefore, for examination purposes, methods which employ antibodies that bind C9, particularly those antibodies that bind to amino acids 359 to 384 of human C9 read on the claimed methods which employ molecules which bind to amino acids 359 to 384 of human C9. The use of such C9-specific antibodies is encompassed by the claimed use of peptidomimetics having the structure of human CD59 amino acid residues 42-58, and binding specifically to amino acids residues 359-384 of human C9.

(6) Issues.

The appellant's statement of the issues in the Brief is correct.

(7) Grouping of Claims.

Appellant's statement in the Brief that certain claims do not stand or fall together is not agreed with because this appeals only involves claims 10-12 and 16-17, as they read on methods which employ antibodies that bind C9, particularly those antibodies that bind to amino acids 359 to 384 of human C9 and inhibit C5b-9 complex assembly and activities, as the elected invention.

It is noted that the rejection under 35 USC 112, first and second paragraphs, has been applied with respect to the scope and metes and bounds of "peptidomimetics" of the generic claims.

However, the art rejections under 35 USC 102 and 103 have been applied only with respect to the elected invention of methods which employ antibodies that bind C9, particularly those antibodies that bind to amino acids 359 to 384 of human C9 and inhibit C5b-9 complex assembly and activities .

Appellant's statement that the claims must be examined separately based on whether or not they require further limitation s as to the chemical structure of the peptidomimetic or go to the method of use is acknowledged.

Again, the claims have been prosecuted and examined as they read on methods which employ antibodies that bind C9, particularly those antibodies that bind to amino acids 359 to 384 of human C9, read as the elected invention.

(8) Claims Appealed.

The copy of the appealed claims contained in the Appendix to the Brief is correct.

This appeal involves claims 10-12 and 16-17 as they read on methods using anti-C9 antibodies as the elected invention.

(9) Prior Art of Record.

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

1) Sims et al., U.S. Patent No. 5,550,108.
2) Chang et al., J. Biol. Chem. 269: 26424-26430 (1994).

(10) Grounds of Rejection.

The following ground(s) of rejection are applicable to the appealed claims.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 10-12 and 16-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

There is insufficient direction or guidance provided to assist one skilled in the art in the selection of such "a peptidomimetic having the structure and function of human CD59 amino acid residues 42-58" commensurate in scope with the claimed methods, nor is there sufficient evidence provided that all such "peptidomimetics " could be used in a practical manner either in vitro or in vivo to inhibit C5b-9 complex. The instant disclosure provides for certain C9-specific antibodies as well as certain CD59-derived constructs (see Examples 1-2 on pages 29-48 of the instant specification). Minor structural differences among structurally related compounds or compositions can result in substantially different biological and pharmacological activities. Therefore, structurally unrelated compounds comprising antibodies, proteins, peptides, nucleic acids and small molecules would be expected to have greater differences in their activities, particularly when these diverse molecules are expected to have a particular three-dimensional structure that is suppose to mimic CD59.

It would require undue experimentation to produce all such possible "peptidomimetics" or molecules without more explicit guidance from the disclosure. It would require undue experimentation to investigate all such "molecules". Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. It appears that undue experimentation would be required of one skilled in the art to practice the claimed "peptidomimetics" commensurate in scope with the claimed invention using the teaching of the specification.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 10-12 and 16-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-12 and 16-17 are indefinite in the recitation of "a peptidomimetic having the structure and function of human CD59 amino acid residues 42-58" because the characteristics of these "peptidomimetics", including as it reads on anti-C9 antibodies, as the elected invention is ambiguous and confusing. This language is vague and indefinite since it encompasses a myriad of different "peptidomimetics" and it is not apparent from the disclosure which particular "peptidomimetics" are being referred to. Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies the claimed "peptidomimetics " encompassed by the claimed invention. The recitation of "peptidomimetics " fails to distinctly claim what that molecule is made up of. Therefore, there is insufficient information and guidance for the metes and bounds of the claimed "peptidomimetics". Here, the claims do not even claim that the antibodies necessarily bind C9, which is the elected invention.

With respect to the elected invention of anti-C9 antibodies; it is not clear that the skilled artisan would indicate that an anti-C9 antibody that inhibits the formation of human C5b-9 complex acts as a "peptidomimetic having the structure and function of CD59" rather than an antibody that binds C9 and inhibits C5b-9 complex formation. The claimed limitations as it reads on the elected invention of an "anti-C9 antibody" as a "peptidomimetic" in this case appears to be confusing.

Appellant has been invited to amend the claims accordingly, particularly with respect to the elected invention.

Under 35 U.S.C. § 102(b) or, in the alternative, Under 35 U.S.C. § 103

Claims 10-12 and 16-17 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sims et al. (U.S. Patent No. 5,550,108) (see entire document). Sims et al. teach the use of anti-C9 antibodies to inhibit C5b-9 complex. This reference differs from the instant methods by not disclosing CD59 per se, however it appears that antibodies that bind C9 which inhibit C5b-9 complex formation would have the inherent properties of the claimed methods. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods of using C9-specific antibodies to inhibit C5b-9 complex formation and complement-mediated inflammation. The burden is on the applicant to establish a patentable distinction between the claimed and referenced methods. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Rejection Under 35 U.S.C. § 103

Claims 10-12 and 16-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sims et al. (U.S. Patent No. 5,550,108) in view of Chang et al. (J. Biol. Chem. 269: 26424-26430, 1994).

Sims et al. teaches the use of anti-C9 antibodies to inhibit C5b-9 complex, which can be used to inhibit complement-mediated inflammatory responses (see entire document). This reference differs from the instant methods by not disclosing CD59 per se, however it appears that antibodies that bind C9 which inhibit C5b-9 complex formation would have the expected properties of the claimed methods.

Chang et al. teach the nature of the interaction between C9 and CD59, including identifying the peptide domain of human C9 that is bound by CD59 (e.g. residues 359-411) and the importance of these interactions in complement-mediated activities (see entire document).

One of ordinary skill in the art at the time the invention was made would have been motivated to select for anti-C9 antibodies that inhibit C5b-9 complex formation in modulating complement-mediated inflammatory responses, including selecting for those anti-C9 antibodies that inhibit CD59-mediated interactions with C9 and the complement cascade. The residues of 359-384 of C9 would have been targeted given the screening for inhibiting C5b-9 complex formation and the role of these residues in CD59 binding, as taught by the references. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(11) Response to Argument

Rejection Under 35 U.S.C. § 112, First Paragraph

Appellant's arguments, have been fully considered but are not found convincing essentially for the reasons of record.

Appellant's comments on the compounds modulating CD59-mediated complement activity, including those compounds which bind to the region of C9 corresponding to human 334-418, more specifically, between amino acids residues 359 -384, is acknowledged.

Appellant asserts that the compounds can be derived using this basic amino acid sequence and the corresponding three dimensional structure within the protein using any of the several techniques known to those skilled in the art, including rational drug design using computer data bases and modeling of peptide/protein-ligand binding, antibodies and anti-idiotypic antibodies generated to the compounds imitating the structure and/or function of the peptide region, including small molecules identified by combinatorial chemistry techniques. In turn, appellant asserts that these compounds or peptidomimetics can be used to inhibit complement by binding to C9 analogously to CD59 or to maintain complement inhibition by blocking CD59 binding to C9.

Appellant relies upon the disclosure of methods and materials to make these peptidomimetics.

Appellant's reliance on certain chimeric peptides described on pages 13-14 and 44-48 of the instant specification as well as antibodies to amino acids of 42-58 of CD59 and antibodies to amino acids of 359-384 of human C9 (the elected invention) is acknowledged. As indicated previously, these particular compounds disclosed in Examples 1-2 on pages 29-48 of the instant specification are considered enabled.

However, the claims are not limited to methods of inhibiting human C5b-9 complex assembly with these enabled compounds. Rather appellant relies upon further experimentation by employing rational drug design and suitable computer software as well as combinatorial chemistry to make other compounds or peptidomimetics not disclosed in the specification.

Appellant argues in conjunction with various legal decisions and the MPEP that the legal standard for enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent application coupled with information known in the art without undue experimentation.

Appellant relies upon the discovery of one short peptide sequence of human CD59 alone is responsible for the species specific binding of CD59 to inhibit formation of the C5b-9 complex.

Appellant further relies upon the ability to download computer programs from the Internet together with the amino acid sequences of the relevant CD59 and C9 molecules to create a three dimensional structure as claimed.

However as pointed out previously and as appellant has acknowledged and the specification discloses; the claimed peptidomimetics encompass a broad range of diverse and structurally distinct molecules, including proteins, peptides, nucleic acids and small molecules. It appears that structural and/or functional requirements of such "peptidomimetics" is the ability of said "peptidomimetic" to structurally mimic human CD59 amino acids 42-58, when these amino acids have the same spatial orientation as when present in the intact molecule and must specifically bind to amino acids 359 to 384 of human C9 and inhibit C5b-9 complex formation.

While the structural properties of said "peptidomimetics" should mimic or correspond to the three dimensional structure of amino acids residues 42-58 of SEQ ID NO: 3; neither the claims nor the specification appears to limit the "peptidomimetics" to such constraints nor clearly defines the structural constraints to said "peptidomimetics". The physical conformation of said three dimensional structures rely upon the complex nature of primary, secondary and tertiary structures. See Rational Drug Design on pages 18-19 of the specification. The specification also discloses a number of modifications or different sources of starting materials that would result in different physical conformations encompassed by the claimed "peptidomimetics". See Detailed Description of the Invention. For example, compounds Identified by Combinatorial Chemistry on pages 17-18 of the specification discloses the reliance on screening a complex mixture of 10^{15} individual sequences and that 1 in 10^{10} RNA molecules folded in such a way as to bind a given ligand. Again as pointed out previously, it appears the key constraints disclosed and claimed are functional one (e.g. to inhibit C5b-9 complex formation and to bind C9) rather than reliance on a structural one (e.g. a particular sequence type). In contrast to appellant's assertions and reliance upon the disclosure in the specification; reliance on structure-based design of pharmaceutical molecules, including those mimicking a three-dimensional structure was not well understood and was not predictable by the skilled artisan at the time the invention was made.

It is noted that the instant Examples disclosed in the specification indicate that varying structural modification impart varying functional properties and that there were certain limitations to those molecules and structures that provide the inhibitory properties and species specificity, encompassed by the claims and asserted by appellant. For example, see pages 38-39 and 47-48 of the instant specification.

It is not sufficient to define a specificity by its principal biological activity, i.e. a peptidomimetic having the structure and function of human CD59 amino acid residues 42-58", which in itself is ill-define, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property or here, both structural and functional properties. See Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992). Thus, appellant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed "peptidomimetics" in manner reasonably correlated with the scope of the claimed methods broadly including any number of "peptidomimetics".

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Given the relative incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the limited disclosure in the specification of certain C9-specific antibodies, CD59-specific antibodies ,and certain chimeric CD59 constructs disclosed in the specification as filed and the broad scope of protection sought in the claims, as it reads on any peptidomimetic over a broad range of diverse and structurally distinct molecules, a rejection under 35 USC 112, first paragraph for lack of enablement has been deemed appropriate. For example, appellant has not disclosed nor provided for nucleic acids and small molecules having the structural and functional properties asserted by appellant nor encompassed by the claimed invention. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. Structurally unrelated compounds encompassed by the claimed peptidomimetics would have been expected to have greater even greater differences in their ability to specifically bind amino acid residues 359-384 of human C9 and mimic the structure of CD59.

Without sufficient guidance, the changes which can be made in the structure of any "peptidomimetic" and still provide or maintain sufficient or the claimed activity and structural conformation is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Appellant's arguments are not found persuasive.

Appellant has been invited to limit the claims to clearly recite the appropriate structurally distinct peptidomimetics (e.g. antibodies, chimeric proteins) and to recite the appropriate structural and functional language to obviate this rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Appellant's arguments have been fully considered but are not found convincing essentially for the reasons of record.

Appellant argues that the skilled artisan would learn from the extensive examples that a very small region of human CD59 is responsible for CD59 species-specific role as a complement inhibitor. Appellant relies upon the disclosure of computer programs and screening assays to provide for the specific function activity incorporated in the independent claim. Accordingly, appellant asserts that the claims are definite to those skilled in the art based on the specification.

However, as appellant has acknowledged and the specification discloses; these peptidomimetics encompass a broad range of diverse and structurally distinct molecules, including proteins, peptides, nucleic acids and small molecules, and do not appear to be limited to any particular structure but rather appear to rely on the ability of the peptidomimetic to inhibit C5b-9 complex formation and to bind C9.

While this "recitation" itself may have some notion of the activity of the "peptidomimetics", appellant should particularly point out and distinctly claim the structural and functional attributes of the claimed "peptidomimetics". Claiming biochemical molecules by the recitation of "a peptidomimetic having the structure and function of the region of the CD59 amino acids residues 42-58" fails to distinctly claim what those "peptidomimetic" is made up of.

For example, there is insufficient objective evidence that the elected invention of anti-CD9 antibodies comprise the structural elements of amino acids residues 42-58 of human CD59. However, given the disclosure of the specification and the elected invention, C9-specific antibodies are simply those antibodies that bind C9 which inhibit the C5b-9 complex. It is noted that for examination purposes; antibodies that bind C9 and inhibit the C5b-9 complex read on the claimed "peptidomimetic". However, given the claim recitation of "peptidomimetic", it is not readily apparent that the skilled artisan would recognize or appreciate that antibodies that bind C9 and inhibit the C5b-9 complex read on the claimed "peptidomimetic". Antibodies are generally not considered peptidomimetics. Here, even claim 12 does not recite that the specificity of the antibody is "C9" (e.g., anti-C9 antibody), which is indeed the elected invention.

The metes and bounds of the structural and functional attributes of the claimed "peptidomimetics" is unclear.

For examination purposes and given the variability of structures that can serve as "peptidomimetics" and the variations of said "peptidomimetics; it appears that structural or functional requirements of such "peptidomimetics" is the ability of said "peptidomimetic" to bind to amino acids residues 359-384 of human C9 and to inhibit C5b-9 complex formation.

Also, given the prosecution history and the election of C9-specific antibodies, methods which employ antibodies that bind C9, particularly those antibodies that bind to amino acids 359 to 384 of human C9 read on the claimed methods which employ molecules which bind to amino acids 359 to 384 of human C9. antibodies

Appellant's arguments are not found persuasive.

As pointed out above; applicant has been invited to limit the claims to clearly recite the structurally distinct antibodies, proteins, peptides, nucleic acids and small molecules and to recite the appropriate structural and functional language.

Under 35 U.S.C. § 102(b) or, in the alternative, Under 35 U.S.C. § 103

Appellant's arguments have been fully considered but are not found persuasive essentially for the reasons of record.

Appellant's argues that Sims et al. simply does not identify CD59 amino acids 42-59 nor that this region binds to amino acid residues 359-384, either explicitly nor implicitly. Appellant asserts that this fact simply was not known until the studies described in this application were performed.

Appellant acknowledges that Sims et al. used antibodies to C9 to inhibit CD59 activity. It is acknowledged that Sims does not disclose which region of CD59 imparts species specificity.

In contrast to appellant's focus on the region of CD59 that is associated with C9, the prior art methods would have inherently met the claimed methods, given the prior art teaching of inhibiting the features of inhibiting C5b-9 complex formation, binding C9, inhibiting CD59 activity and inhibiting C5b-9 complex-mediated activities, as acknowledged by appellant.

Appellant asserts that page 47 of the instant specification to support the notion that obtaining an antibody of the claimed invention was extremely unlikely.

In contrast to appellant's assertions, no such statement is made on page 47 of the instant specification. Rather, page 47 of the instant specification discloses that "CD59 is known to bind to C9 after C9 incorporates into the C5b-9 complex and through this interaction inhibit propagation of membrane-inserted C9 polymer, limiting lytic activity of MAC. In order to confirm the importance of the peptide segment recognized by CD59 to MAC assembly, Fab of antibody raised against the hu C9 peptide 359-384 was tested for its capacity to inhibit the hemolytic activity of the hu C5b-9 complex, under the same condition used to evaluate the inhibitory function of CD59."

It appears that the disclosure on page 47 of the instant specification confirms the structural region associated with the interaction between CD59 and C9 and the properties of anti-C9 antibodies of blocking C5b-9 complex formation and inhibiting CD59 activity known in the prior art are consistent with this characterization of the specific region of CD59 involved with C9.

Also, as pointed out previously and indicated herein; for examination purposes, it appears that as the elected invention, C9-specific antibodies are simply those antibodies that bind C9 which inhibit the C5b-9 complex. It is noted that for examination purposes; antibodies that bind C9 and inhibit the C5b-9 complex read on the claimed "peptidomimetic".

Sims et al. teach the use of anti-C9 antibodies to inhibit C5b-9 complex, to inhibit CD59 activity as well as inhibiting C5b procoagulant and prothrombotic responses and complement mediated disorders. (see entire document, including column 5, paragraph 1 and columns 14-16). Given the prior art methods employing C9-specific antibodies, which have the same properties encompassed by the claimed invention, the claimed functional limitations would be inherent properties of the referenced methods of using C9-specific antibodies, including those anti-C9 antibodies that bind to amino acids residues 359-384 of human C9, to inhibit C5b-9 complex formation and complement-mediated inflammation. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

The burden is on the appellant to establish a patentable distinction between the claimed and referenced methods.

Appellant has not provided sufficient objective evidence to distinguish the claimed and referenced methods which appear to employ the same C9-specific antibodies which inhibit C5b-9 complex formation and complement-mediated inflammation. Appellant appears to rely upon the characterization or confirmation of properties or structural motif(s) associated with those C9-specific antibodies which inhibit C5b-9 complement-mediated interactions and more particularly C5b-9 complement-mediated procoagulant and prothrombotic activities. Again, given the claimed language and the elected invention, C9-specific antibodies which bind C9 and inhibit the C5b-9 complex, including associated complement-mediated activities in various diseases and conditions meets the claimed methods..

The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01 (C).

It is noted that prior art relies upon the work of applicant and yet applicant has not indicated that the prior art methods of inhibiting complement C5b-9 complex activity with anti-C9 antibodies do not meet the claimed limitations.

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

For example, Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) states: "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Appellant's arguments are not found persuasive.

Rejection Under 35 U.S.C. § 103

Appellant's arguments have been fully considered but are not found persuasive essentially for the reasons of record.

Appellant argues in conjunction with a number of legal decisions that the prior art must suggest the claimed invention and the prior art must indicate the invention would have a reasonable likelihood of success.

Appellant argues that Sims et al. does not teach what region of CD59 imparts species-specificity.

Appellant argues that Chang et al. identifies the region of human C9 which is bound by human CD59, not the portion of CD59 which binds and asserts that one cannot extrapolate from the information relating to human C9 to obtain information about human CD59.

Appellant argues that the requirement for binding to a specific region of C9 is a specific limitation of the claimed compounds and that there is no teaching in the art leading one to this limitation nor is it obvious.

However as pointed out previously and indicated above; for examination purposes, it appears that as the elected invention, C9-specific antibodies are simply those antibodies that bind C9, including anti-C9 antibodies that bind amino acids residues 359-384 of human C9, which inhibit the C5b-9 complex. It is noted that for examination purposes; antibodies that bind C9 and inhibit the C5b-9 complex read on the claimed "peptidomimetic".

Sims et al. teach the use of anti-C9 antibodies to inhibit C5b-9 complex and that antibodies that bind C9 which inhibit C5b-9 complex formation would have the expected properties of the claimed methods (see entire document, including column 5, paragraph 1 and columns 14-16). The claimed functional limitations would be expected properties of the referenced methods of using C9-specific antibodies to inhibit C5b-9 complex formation and complement-mediated inflammation.

As indicted above, appellant acknowledges that Sims et al. used antibodies to C9 to inhibit CD59 activity. It is acknowledged that Sims does not disclose which region of CD59 imparts species specificity.

As pointed out previously, Chang et al. teach the nature of the interaction between C9 and CD59, including identifying the peptide domain of human C9 that is bound by CD59 (e.g. residues 359-411) and the importance of these interactions in complement-mediated activities (see entire document, including Abstract, Results and Discussion). Here, Chang et al. conducts studies on the CD59 binding site on C9 and determines that the binding site for CD59 is encompassed by residues 320-411 with much of the affinity of this site contributed by C9 residues 359-411 (see Abstracts, Results and Discussion, including page 26427, column 2, lines 5-10). In contrast to appellant's assertions, there is direction to the same or nearly the same region of C9 that is critical to CD59 binding and affinity, as encompassed by the claimed invention.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to select for anti-C9 antibodies that inhibit C5b-9 complex formation in modulating complement-mediated inflammatory responses, including selecting for those anti-C9 antibodies that inhibit CD59-mediated interactions with C9 and the complement cascade. The residues of 359-384 of C9 would have been targeted given the screening for inhibiting C5b-9 complex formation and the role of these residues in CD59 binding, as taught by the references.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Appellant's arguments are not found persuasive.

Appellant's arguments are not found persuasive

(13) For the above reasons, it is believed that the rejections should be sustained.

Respectively submitted,

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